# Intra-Cellular Therapies Reports Third Quarter 2021 Financial Results and Provides Corporate Update

November 9, 2021

*CAPLYTA supplemental new drug applications (sNDAs) for the treatment of bipolar depression are under review by the FDA, with a PDUFA target action date of December 17, 2021.*

*Bipolar depression launch preparations are progressing well; sales force expansion is substantially complete.*

*Total revenues were $22.2 million for the third quarter of 2021, compared to $7.4 million for the same period in the prior year, representing an increase of approximately 200%.*

*CAPLYTA achieved net product revenues of $21.6 million for the third quarter of 2021. Third quarter CAPLYTA total prescriptions (TRx) increased 15% versus the previous quarter.*

*Patient enrollment is ongoing in a pivotal program evaluating lumateperone as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD).*

NEW YORK, Nov. 09, 2021 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (Nasdaq: ITCI), a biopharmaceutical company focused on the development and commercialization of therapeutics for central nervous system (CNS) disorders, today announced its financial results for the third quarter ended September 30, 2021 and provided a corporate update.

“We are excited about the progress we have made during the third quarter in the commercialization of CAPLYTA in schizophrenia and in the advancement of our development programs. In addition, our bipolar depression launch preparations are progressing well and we have substantially completed our sales force expansion,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

**Third Quarter Financial Highlights**

- Total revenues were $22.2 million for the third quarter of 2021, compared to $7.4 million of total revenues for the third quarter of 2020. Net product revenues of CAPLYTA were $21.6 million for the third quarter of 2021, compared to $7.4 million in net product revenues of CAPLYTA for the same period in 2020.
- Cost of product sales were $2.0 million in the third quarter of 2021 compared to $0.6 million for the same period in 2020.
- Research and development (R&D) expenses for the third quarter of 2021 were $27.0 million, compared to $10.3 million for the third quarter of 2020. This increase is due to higher lumateperone clinical trial costs and an increase in other development program costs.
- Selling, general and administrative (SG&A) expenses were $70.5 million for the third quarter of 2021, compared to $52.5 million for the same period in 2020. This increase is primarily due to an increase in marketing and commercialization costs.
- Net loss for the third quarter of 2021 was $76.9 million compared to a net loss of $55.2 million for the same period in 2020.
- Cash, cash equivalents, restricted cash and investment securities totaled $478.7 million at September 30, 2021, compared to $658.8 million at December 31, 2020.

**COMMERCIAL HIGHLIGHTS**

- Bipolar depression launch preparations continue to progress, and we have substantially completed our sales force expansion. If approved, we expect to launch CAPLYTA in bipolar depression immediately following U.S. Food and Drug Administration (FDA) approval.
- Our hybrid commercialization model, combining virtual and in-person engagements, and our digital marketing initiatives continue to deliver consistent revenue and prescription growth despite COVID-19 disruptions affecting the medical care of patients with schizophrenia.
- Third quarter CAPLYTA results reflect continued prescription growth, increasing total prescriptions by 15% versus the

second quarter of 2021 and approximately 200% versus the same period in 2020.

**CLINICAL HIGHLIGHTS**

R&D Day Highlighting Development Programs:

- The Company hosted an R&D day highlighting its research and development programs. Presentations and discussions from the Company's management team and external key opinion leaders described different aspects of our broad pipeline, including our lumateperone, ITI-1284, PDE1 inhibitors and ITI-333 platforms.

Lumateperone:

- Bipolar Depression Program: The lumateperone sNDAs for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate are under review by the FDA. The Prescription Drug User Fee Act (PDUFA) target action date is December 17, 2021 for these applications.
- Adjunctive MDD program: Patient enrollment has been initiated in global studies 501 and 502. These are Phase 3 double blind, placebo-controlled, 6-week studies evaluating lumateperone 42mg as adjunctive treatment to anti-depressants for patients having an inadequate response to antidepressant therapy. The primary endpoint is change from baseline versus placebo on the MADRS total score at week 6, and the CGI-S scale is the key secondary endpoint.
- Mixed Features program: Study 403 is ongoing and is evaluating lumateperone 42mg in patients with MDD and in patients with bipolar depression who exhibit mixed features. We expect to complete this study in the second half of 2022.
- Lumateperone Long Acting Injectable (LLAI) formulation: Study ITI-007-025, a Phase 1 single ascending dose study of LLAI, is ongoing. We expect to complete this study later this year.
- Publications: Announced the publication of Study 404, a Phase 3 clinical study evaluating lumateperone as monotherapy in patients with bipolar depression. The article titled "Efficacy and Safety of Lumateperone for Major Depressive Episodes Associated with Bipolar I or Bipolar II Disorder: A Phase 3 Randomized Placebo-Controlled Trial," was published online in The American Journal of Psychiatry.

Other Programs:

- ITI-1284 program: We have initiated our program for the development of ITI-1284-ODT-SL for the treatment of agitation in patients with probable Alzheimer's disease. Clinical conduct in this program is expected to commence early in 2022. Studies in dementia-related psychosis and certain depressive disorders in the elderly are planned for the first half of 2022.
- Phosphodiesterase type I inhibitor (PDE1) program:
    - Our Phase 2 clinical program evaluating lenrispodun (ITI-214) in Parkinson's disease has been initiated, and we expect to commence patient enrollment in the first half of 2022.
    - We announced four publications highlighting the beneficial effects of PDE1 inhibition with lenrispodun on cardiovascular function in patients with heart failure and in age-related vascular changes in preclinical models associated with stiffening of arteries, vascular endothelial dysfunction, and increased inflammation. In addition, a novel cellular mechanism by which PDE1 stimulates cardiac contraction was described in one of these studies. These findings have broad implications, as cardiovascular dysfunction and inflammation play important roles across multiple chronic and age-related diseases.
- ITI-333 program in opioid use disorder: ITI-333 is a novel compound that acts as a partial agonist at mu-opioid (MOP) receptors and as antagonists at the serotonin 5HT2A receptors. At MOP receptors, it acts as a partial agonist signaling through G-protein pathways, but it acts as an antagonist at beta-arrestin pathways. These characteristics and results from early clinical and preclinical models highlight the potential of ITI-333 to address important unmet therapeutic needs in opioid use disorder and pain. A Phase 1 single ascending dose study, evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers, is ongoing. Results from this study are anticipated in the fourth quarter of 2021.

**Conference Call and Webcast Details**

The Company will host a live conference call and webcast today at 8:30 AM Eastern Time to discuss the Company's financial results and provide a corporate update. The live webcast and subsequent replay may be accessed by visiting the Company's website at www.intracellulartherapies.com. Please connect to the Company's website at least 5-10 minutes prior to the live webcast to ensure adequate time for any necessary software download. Alternatively, please call 1-(844) 835-6563 (U.S.) or 1-(970) 315-3916 (international) to listen to the live conference call. The conference ID number for the live call is 3650108. Please dial in approximately 10 minutes prior to the call.

CAPLYTA® (lumateperone) is indicated for the treatment of schizophrenia in adults. CAPLYTA is available in 42 mg capsules.

**Important Safety Information**

**Boxed Warning: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.**

**Contraindications:** CAPLYTA is contraindicated in patients with known hypersensitivity to lumateperone or any components of CAPLYTA. Reactions have included pruritus, rash (e.g., allergic dermatitis, papular rash, and generalized rash), and urticaria.

**Warnings & Precautions:** Antipsychotic drugs have been reported to cause:

- **Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis**, including stroke and transient ischemic attack. See Boxed Warning above.
- **Neuroleptic Malignant Syndrome (NMS)**, which is a potentially fatal reaction. Signs and symptoms include: high fever, stiff muscles, confusion, changes in breathing, heart rate, and blood pressure, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Patients who experience signs and symptoms of NMS should immediately contact their doctor or go to the emergency room.
- **Tardive Dyskinesia**, a syndrome of uncontrolled body movements in the face, tongue, or other body parts, which may increase with duration of treatment and total cumulative dose. TD may not go away, even if CAPLYTA is discontinued. It can also occur after CAPLYTA is discontinued.
- **Metabolic Changes**, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.
- **Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases)**. Complete blood counts should be performed in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. CAPLYTA should be discontinued if clinically significant decline in WBC occurs in absence of other causative factors.
- **Decreased Blood Pressure & Dizziness**. Patients may feel lightheaded, dizzy or faint when they rise too quickly from a sitting or lying position (orthostatic hypotension). Heart rate and blood pressure should be monitored and patients should be warned with known cardiovascular or cerebrovascular disease. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension.
- **Falls**. CAPLYTA may cause sleepiness or dizziness and can slow thinking and motor skills, which may lead to falls and, consequently, fractures and other injuries. Patients should be assessed for risk when using CAPLYTA.
- **Seizures**. CAPLYTA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Sleepiness and Trouble Concentrating**. Patients should use caution when operating machinery or motor vehicles until they know how CAPLYTA affects them.
- **Body Temperature Dysregulation**. CAPLYTA should be used with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.
- **Dysphagia**. CAPLYTA should be used with caution in patients at risk for aspiration.

**Drug Interactions:** CAPLYTA should not be used with CYP3A4 inducers, moderate or strong CYP3A4 inhibitors and UGT inhibitors.

**Special Populations:** Newborn infants exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Breastfeeding is not recommended. Use of CAPLYTA should be avoided in patients with moderate or severe liver problems.

**Adverse Reactions:** The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation (24% vs. 10%) and dry mouth (6% vs. 2%).

Please click here to see full Prescribing Information including **Boxed Warning**.

**About CAPLYTA (lumateperone)**

CAPLYTA 42mg/day is an oral, once daily atypical antipsychotic approved for the treatment of schizophrenia of adults. While the mechanism of action of CAPLYTA in the treatment of schizophrenia is unknown, the efficacy of CAPLYTA could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors.

Lumateperone is being investigated for the treatment of bipolar depression, depression and other neuropsychiatric and neurological disorders. CAPLYTA is not FDA approved for these disorders.

**About Intra-Cellular Therapies**

Intra-Cellular Therapies is a biopharmaceutical company founded on Nobel prize-winning research that allows us to understand how therapies affect the inner-workings of cells in the body. The company leverages this intracellular approach to develop innovative treatments for people living with complex psychiatric and neurologic diseases. For more information, please visit www.intracellulartherapies.com.

**Forward-Looking Statements**

This news release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, our expectations regarding the commercialization of CAPLYTA; our expectations regarding the sNDAs, including the adequacy of the data contained in the sNDAs to serve as the basis for approval of lumateperone for the treatment of depressive episodes associated with bipolar I or II disorder both as monotherapy and as adjunctive therapy in adults; the potential approval by the FDA of the sNDAs for lumateperone for the treatment of bipolar depression; the potential timing of review and action by the FDA with respect to the sNDAs; our plans and expected timing for completion of Study 403; our plans and expected timing for results from our lumateperone long-acting injectable clinical trial; our plans and expected timing for results from our ITI-333 clinical trial; our development plans for our PDE program, including lenrispodun (ITI-214) and our expected timing to commence patient enrollment, and the potential benefits of PDE1 inhibition; our plans and expected timing for the initiation of our ITI-1284 programs; our beliefs about the potential utility of our product candidates; and development efforts and plans under the caption “About Intra-Cellular Therapies.” All such forward-looking statements are based on management’s present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to, the following: whether the preclinical and clinical results of the lumateperone studies will meet the regulatory requirements for approval by the FDA for the proposed indications; whether the sNDAs will be approved by the FDA and whether the FDA will complete its review within its target timelines, including its target action date; whether the FDA will require additional information, whether we will be able to provide in a timely manner any additional information that the FDA requests, and whether such additional information will be satisfactory to the FDA; our ability to launch CAPLYTA in bipolar depression immediately following an approval; there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in commercializing CAPLYTA; the COVID-19 pandemic may negatively impact our commercial plans and sales for CAPLYTA; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials; whether CAPLYTA receives adequate reimbursement from third-party payors; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indication; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in CAPLYTA in the treatment of schizophrenia following commercial launch of the product may be different than observed in clinical trials, and may vary among patients; any other impacts on our business as a result of or related to the COVID-19 pandemic; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA following commercial launch for the treatment of schizophrenia or in ongoing or future trials and other development activities; our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials or in clinical trials for other indications; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; our reliance on collaborative partners and other third parties for development of our product candidates; and the other risk factors detailed in our public filings with the Securities and Exchange Commission. All statements contained in this press release are made only as of the date of this press release, and we do not intend to update this information unless required by law.

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**INTRA-CELLULAR THERAPIES, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2021** | 2020 | **2021** | 2020 |
| Revenues | | | | |
| Product sales, net | **$ 21,606,163** | $ 7,368,594 | **$ 56,191,848** | $ 10,126,999 |
| Grant revenue | **601,038** | — | **1,940,243** | 231,710 |
| Total revenues | **22,207,201** | 7,368,594 | **58,132,091** | 10,358,709 |
| Operating expenses: | | | | |
| Cost of product sales | **2,001,315** | 556,107 | **5,496,561** | 753,957 |
| Research and development | **27,031,825** | 10,275,368 | **59,386,413** | 51,483,551 |
| Selling, general and administrative | **70,497,885** | 52,473,573 | **192,932,688** | 128,015,496 |
| Total operating expenses | **99,531,025** | 63,305,048 | **257,815,662** | 180,253,004 |
| Loss from operations | **(77,323,824)** | (55,936,454) | **(199,683,571)** | (169,894,295) |

| | | | | |
|---|---|---|---|---|
| Interest income | **392,695** | 752,829 | **1,297,473** | 3,591,091 |
| Loss before provision for income taxes | **(76,931,129)** | (55,183,625) | **(198,386,098)** | (166,303,204) |
| Income tax (expense) benefit | **23,125** | — | **(5,631)** | (3,281) |
| Net loss | **$ (76,908,004)** | $ (55,183,625) | **$ (198,391,729)** | $(166,306,485) |
| Net loss per common share: | | | | |
| Basic & Diluted | **$ (0.95)** | $ (0.79) | **$ (2.44)** | $ (2.48) |
| Weighted average number of common shares: | | | | |
| Basic & Diluted | **81,354,724** | 69,530,039 | **81,178,482** | 67,030,991 |

The condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020 have been derived from the financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

**INTRA-CELLULAR THERAPIES, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

| | **September 30, 2021** | December 31, 2020 |
|---|---|---|
| | **(Unaudited)** | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | **$ 106,125,959** | $ 60,045,933 |
| Investment securities, available-for-sale | **371,157,974** | 597,402,126 |
| Restricted cash | **1,400,000** | 1,400,000 |
| Accounts receivable, net | **16,934,352** | 10,764,583 |
| Inventory | **8,166,935** | 7,056,385 |
| Prepaid expenses and other current assets | **29,457,445** | 14,235,455 |
| Total current assets | **533,242,665** | 690,904,482 |
| Property and equipment, net | **1,936,308** | 1,998,346 |
| Right of use assets, net | **21,710,677** | 24,324,762 |
| Other assets | **86,084** | 86,084 |
| Total assets | **$ 556,975,734** | $ 717,313,674 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | **$ 12,030,614** | $ 5,501,825 |
| Accrued and other current liabilities | **16,928,669** | 10,902,117 |
| Lease liabilities, short-term | **6,082,054** | 5,541,802 |
| Accrued employee benefits | **14,854,226** | 14,907,479 |
| Total current liabilities | **49,895,563** | 36,853,223 |
| Lease liabilities | **20,323,918** | 23,600,347 |
| Total liabilities | **70,219,481** | 60,453,570 |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value: 175,000,000 and 100,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 81,377,406 and 80,463,089 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively | **8,138** | 8,046 |
| Additional paid-in capital | **1,622,149,674** | 1,593,475,506 |
| Accumulated deficit | **(1,135,495,761)** | (937,104,032) |
| Accumulated comprehensive income | **94,202** | 480,584 |
| Total stockholders' equity | **486,756,253** | 656,860,104 |
| Total liabilities and stockholders' equity | **$ 556,975,734** | $ 717,313,674 |

(1) The condensed consolidated balance sheets at September 30, 2021 and December 31, 2020 have been derived from the financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.


Source: Intra-Cellular Therapies Inc.